Nos. 15-2145, 15-2147

IN THE

United States Court of Appeals for the Fourth Circuit

UNITED STATES OF AMERICA *ex rel.* BRIANNA MICHAELS and AMY WHITESIDES,
Plaintiffs-Appellants,

v.

AGAPE SENIOR COMMUNITY, INC., *et al.*,
Defendants-Appellees.

v.

UNITED STATES OF AMERICA,
Intervenor-Appellee.

On Appeal from the United States District Court
for the District of South Carolina
No. 0:12-cv-03466-JFA (Anderson, J.)

BRIEF FOR AMICI CURIAE THE AMERICAN HOSPITAL ASSOCIATION AND THE CATHOLIC HEATH ASSOCIATION OF THE UNITED STATES IN SUPPORT OF DEFENDANTS-APPELLEES

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RULE 26.1 CORPORATE DISCLOSURE STATEMENT

The American Hospital Association (AHA) has no parent company and no publicly held company holds more than a ten percent interest in AHA.

The Catholic Health Association of the United States (CHA) has no parent company and no publicly held company holds more than a ten percent interest in CHA.

In addition, no other publicly held corporation or other publicly held entity has a direct financial interest in the outcome of the litigation within the meaning of Local Rule 26.1(b).

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STATEMENT OF INTEREST OF AMICUS CURIAE

The American Hospital Association (AHA) and The Catholic Health Association of the United States (CHA) respectfully submit this brief as amici curiae in support of the Agape Defendants-Appellees.[1]

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[1] Pursuant to Federal Rule of Appellate Procedure 29, AHA and CHA certify that no party's counsel authored this brief in whole or in part; no party or party's counsel contributed money intended to fund the brief's preparation or submission; and no person other than AHA, CHA, and their members and counsel contributed money intended to fund the brief's preparation or submission. The Agape Appellees and the United States consented to the filing of this brief; Appellants did not consent, and thus AHA and CHA have filed a motion for leave to file this brief.

Founded in 1898, AHA is the national advocacy organization for hospitals in this country. It represents more than 5,000 hospitals, health care systems, and other health care organizations, plus nearly 43,000 individual members. AHA's mission is to promote high quality health care and health services through leadership and assistance to hospitals in meeting the health care needs of their communities. AHA advocates on behalf of its members in legislative, regulatory, and judicial fora as part of its commitment to improving health care policy and health care delivery for the communities that its members serve.

CHA is the national leadership organization for the Catholic health ministry. Comprised of more than 600 hospitals and 1,400 long-term care and other health facilities in all 50 states, the Catholic health ministry is the largest group of nonprofit health care providers in the nation. CHA works to advance the ministry's commitment to a just, compassionate health care system and to ensure that the nation's health system provides quality, affordable care across the continuum of health care delivery.

The relators in this case allege that claims submitted to the government by the Appellees for hospice care were "false or fraudulent" under the False Claims Act (FCA), 31 U.S.C. § 3729, because physicians should not have found the patients eligible for hospice treatment or at least not for the level of hospice treatment they received. The issue on appeal is whether relators must prove that

each claim for which they seek statutory damages and penalties was, in fact, false or fraudulent or whether they can use statistical sampling and extrapolation to shortcut actually reviewing—or presenting any evidence about—the facts of a patient's medical history, diagnosis, age, prior or co-existing medical conditions, or any other factors that the physician relied on in making a clinical judgment about hospice eligibility.

The statistical sampling issue is critically important to AHA's and CHA's member hospitals, which submit thousands of claims to Medicare and Medicaid every day based on physicians' medical judgments about patient conditions and courses of treatment.[2] AHA and CHA know firsthand that statistical analyses are no substitute for the on-the-ground medical context a treating physician knows, understands, and relies upon in making treatment decisions for a given patient.

The FCA does not allow such shortcutting of proof that a claim was false. Because it is a fraud statute, FCA cases based on the exercise of a physician's

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[2] For example, Medicare covers inpatient hospital stays "based upon the admitting physician's clinical judgment that a patient will require hospital care that is expected to span at least 2 midnights" and permits exceptions on a case-by-case basis "for stays expected to last less than the 2-midnight benchmark, based upon the admitting physician's clinical judgment that inpatient hospital admission is appropriate." *Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Short Inpatient Hospital Stays; Transition for Certain Medicare-Dependent, Small Rural Hospitals Under the Hospital Inpatient Prospective Payment System; Provider Administrative Appeals and Judicial Review*, 80 Fed. Reg. 70,298, 70,541 (Nov. 13, 2015).

medical judgment about patient care can only result in treble damages and per-claim penalties if there is proof that the physician's treatment decision was so unreasonable in light of the patient's medical condition that it amounted to fraud on the United States. That showing cannot be made without actually reviewing and analyzing the documented medical history, diagnosis, and other information that the doctor relied upon in making treatment decisions for a particular patient.

Each and every patient for which AHA's and CHA's member hospitals submit claims to the government is under the care of a physician. As a result, each and every service that a patient receives is based on the medical judgment of a physician—from whether to admit a patient, to which tests, medications, and therapies to provide, to when to discharge the patient. These physician judgment calls are specific to the individual and based on each patient's unique condition and needs. The District Court acknowledged as much when it explained that "each and every claim at issue in this case is fact-dependent and wholly unrelated to each and every other claim." Dkt. No. 296, at 4.

The notion that liability in a medical-judgment FCA case could proceed based on extrapolation is extremely alarming to AHA and CHA. The majority of the services amici's members provide are reimbursed by government health care programs, which makes AHA's and CHA's members attractive targets for relators. And there is no question relators are focused on health care providers: During

2015, 70% of *qui tam* suits filed under the FCA named defendants in the health care field.

If the falsity of claims involving medical judgment could be proven through statistical sampling rather than an analysis of the facts and circumstances of a patient's unique situation, the consequences to health care providers would be hard to overstate. The FCA combines a lucrative bounty provision, treble-damages, per-claim penalties, and an attorney fee-shifting provision. Unsurprisingly, then, the statute has become the tool of choice for asserting liability for alleged provider missteps when navigating the regulatory world of federal healthcare programs—a regime courts have characterized as byzantine. Endorsing liability based on statistical sampling rather than an analysis of patient-specific medical histories, diagnoses, and other information that doctors use to reach treatment decisions would improperly lower relators' burden of proof in these cases. It would also undermine defendants' capacity to defend themselves by, for example, offering testimony and analysis substantiating the reasonableness of the treatment decision in the context of each patient's circumstances. The combination of lowering the burden of proof and truncating a defendant's ability to defend itself would only further incentivize the filing of questionable and meritless *qui tam* suits.

AHA and CHA believe that before punitive treble damages and per-claim penalties can be imposed, a relator must prove facts demonstrating that a claim is

false. Statistics are not enough—particularly in cases that turn on clinical judgments made by doctors reviewing real facts about real patients. Defending against meritless FCA suits is already an expensive undertaking that diverts needed resources from providing patient care. AHA and CHA thus support Agape's position that the District Court correctly denied the relators' request to prove that individual claims for payment submitted by Agape were "false claims" through statistical sampling.

SUMMARY OF ARGUMENT

In their statistical sampling argument, Relators seek to have their proverbial cake and eat it too. This Court has previously held—at the urging of the government and relators—that each separate claim submitted to the government constitutes a separate violation of the FCA. The government and relators benefit from that rule, because it subjects defendants to the statutory penalty of up to $11,000 for *each* alleged false claim. In a case like this, involving tens of thousands of allegedly false claims, the potential liability can be catastrophic. There is, however, a corollary to that rule—and an essential safeguard against its abuse: each claim must be separately proved. That is, if a relator wants to collect treble damages and the statutory penalty for a particular claim, he must show the elements of FCA liability as to *that specific claim*.

The relators here, and others like them, ask courts to impose draconian liability without requiring them to analyze the facts and circumstances of the vast majority of the claims that they say are fraudulent. That is not how liability under the statute works. Relators' argument is inconsistent with this Court's precedent on related issues and would create a litigation framework akin to the "Trial by Formula" rejected by the Supreme Court in *Wal-Mart Stores, Inc. v. Dukes*, 131 S. Ct. 2541 (2011).

Whether a relator alleges that a defendant submitted a single false claim, 10 false claims, or 10,000 false claims, he must prove the falsity of each claim (and the other elements of the cause of action) in order to obtain treble damages and per-claim penalties for that claim. It would be nonsensical for the burden of proof to vary based on the volume of claims a relator chooses to plead. In fact, in a case involving thousands of allegedly false claims, this Court already held that statistics are not sufficient to meet a plaintiff's burden even when they suggest a mathematical likelihood that false claims exist. *See U.S. ex rel. Nathan v. Takeda Pharm. N. Am., Inc.*, 707 F.3d 451 (4th Cir. 2013), *cert. denied*, 134 S. Ct. 1759 (2014). There, the Court affirmed dismissal of a relator's complaint on the basis that the relator's proffered statistical analysis "fail[ed] to allege *directly* that any of the identified" claims were false, "instead requiring that a court draw an implausible inference linking general statistics to the" particular claims. *Id.* at 459

(emphasis added). It defies common sense that allegations deemed insufficient to plausibly state a claim could somehow be morphed into sufficient evidence to impose liability.

The notion that a court should lessen the burden of proof applicable to a plaintiff's claim because it would be costly in time and dollars for a plaintiff to meet that burden is equally unfounded. A plaintiff is always the master of his own complaint; it rings hollow for a relator who chooses to allege wide-ranging and varied schemes involving many different physicians and many different medical facilities over the course of many years to later complain that it will be expensive to hire an expert to substantiate those allegations. Moreover, the FCA standard is exacting precisely because of the essentially punitive liability the FCA authorizes. The statute is not designed to make it easy or routine for financially motivated relators to attempt to collect large judgments or settlements by second guessing doctors' medical judgments. Instead, for every claim a relator says warrants treble damages and penalties, he must stand behind it and prove it.

Any contrary ruling—permitting FCA relators to prove liability on questions of medical judgment using extrapolation rather than looking to the facts underlying the medical judgment—would be disastrous to hospitals and the health care field more broadly. The number of FCA suits has skyrocketed in recent years, while the percentage of suits in which the United States actually intervenes has dwindled.

Most suits now proceed without the oversight or restraint of the federal government, regardless of how meritless they are. And because health care organizations interact with Medicare and Medicaid so frequently, they are uniquely exposed to *qui tam* relators who are financially motivated to lower the bar for proof of FCA violations. In recent years, 70% of *qui tam* suits filed under the FCA have involved the health care field.

Medical-judgment FCA cases turn on whether there was any reasonable basis for the physician's clinical judgment. Statistical sampling cannot be used to shortcut such proof. If it could, providers like AHA's and CHA's members would lose a crucial means of defending themselves; they could not put the actual facts underlying each claim before the jury. Perversely, the bigger a relator's allegations, the lower his burden of proof would become; the result would be more health care providers forced into costly defense of meritless FCA suits and more *in terrorem* settlements. That situation would divert money away from patient care and increase the cost of health care for everyone.

This Court should affirm the District Court's ruling that statistical sampling cannot be used to eliminate a relator's burden to prove that the exercise of medical judgment underlying particular claims rendered those claims "false or fraudulent."

ARGUMENT

I. WHEN THE FALSITY OF A CLAIM DEPENDS ON A DOCTOR'S MEDICAL JUDGMENT ABOUT A PATIENT'S CONDITION, RELATORS CANNOT PROVE LIABILITY THROUGH STATISTICAL SAMPLING.

The relators here allege that a network of nursing homes submitted thousands of false claims for hospice services because a physician should not have found the patients eligible for hospice services at all or at least not for the type of hospice services they received. Relators' Br. 2, 4. As the District Court explained—and the relators do not contest on appeal—to determine whether each claim was false requires an assessment of "whether certain services furnished to nursing home patients were medically necessary," which necessitates a "fact-intensive inquiry involving medical testimony after a thorough review of the detailed medical chart of each individual patient." Dkt. No. 296, at 17. Yet the relators insist that a review of each chart and an assessment of each medical judgment should not be required, essentially because it would be expensive and time-consuming for their expert to conduct the fact-intensive inquiry necessary to review the medical judgments involved. Relators' Br. 4.

But the FCA expressly directs that relators are "required to prove all essential elements of the cause of action," 31 U.S.C. § 3731(d), and one of those elements is that the claims at issue are false. Relators cannot obtain a liability ruling in their favor on claims they decline to analyze and prove resulted from

fraudulent medical judgments. A contrary holding would mean that relators in medical-judgment cases would not have to provide any evidence that there was no reasonable basis for a doctor's medical judgment in treating a particular patient. Indeed, a relator's expert would not even have to review the vast majority of medical records or claims that are allegedly FCA violations. The FCA does not provide for this kind of shortcut.[3]

A. FCA Relators Must Prove Liability On A Claim-By-Claim Basis.

Under this Court's precedent, *each* false claims constitutes a *separate* violation of the FCA, and therefore each false claim must be separately proved. When a defendant "submit[s] numerous invoices for reimbursement" to the government, "*each* [one] constitutes a 'claim' under the False Claims Act." *Harrison v. Westinghouse Savannah River Co.*, 176 F.3d 776, 792 (4th Cir. 1999). (emphasis added); *see also U.S. ex rel. Drakeford v. Tuomey*, 792 F.3d 364, 386 (4th Cir. 2015) ("each [reimbursement] form constituted a separate claim"). Whether a relator brings a lawsuit with respect to an individual claim for medical services or many claims, the FCA elements remain the same.

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[3] In contrast, the District Court below proposed—and both parties agreed to conduct—a manageable bellwether trial over whether claims submitted for a small subset of patients violated the FCA. Dkt. No. 296, at 4. This sort of trial would hold relators to their burden of proof as to each claim submitted in connection with those patients; the parties could then use the outcome of the trial as they saw fit for further settlement negotiations or strategic assessments of the merits of the case.

Treating each claim as a separate violation is generally a boon to relators and the government, because each claim is then subject to a statutory penalty. The per-claim penalties quickly add up to potentially staggering liability. *See, e.g.*, *U.S. ex rel. Bunk v. Gosselin World Wide Moving, N.V.*, 741 F.3d 390, 407 (4th Cir. 2013). That is why the government has constantly insisted that liability—and the statutory penalty—attaches to each claim individually. *See, e.g.*, Brief of the United States in Opposition to *Certiorari* at 16, No. 13-1399, *Gosselin World Wide Moving, N.V.* v. *Bunk* (U.S. 2014) ("[E]ach time a defendant presents a false claim for payment, his conduct triggers the statutory civil penalty.").

But relators and the government must take the bitter with the sweet: If the FCA imposes liability and a statutory penalty for each individual claim, then it follows that each claim must be individually proved. If a relator brings suit to recover for only one allegedly false claim, he must prove the falsity of *that particular claim* (as well as the other elements of a FCA violation) to recover treble damages and the statutory penalty. *U.S. ex rel. Harrison v. Westinghouse Savannah River Co.*, 352 F.3d 908, 913 (4th Cir. 2003). If a relator brings suit over five claims, he cannot prove the falsity of three and ask for an inference that the rest were false too. *See* John T. Boese, *Civil False Claims and Qui Tam Actions* § 2.03[D][1], at 2-168.3 (4th ed. Supp. 2015). That basic principle does not change depending on the number of claims at issue.

In *U.S. ex rel. Nathan v. Takeda Pharmaceuticals North America, Inc.*, 707 F.3d 451 (4th Cir. 2013), this Court held that statistical evidence is not enough to *plausibly plead* FCA liability; the logical import of that holding is that statistical evidence is not enough to *definitively establish* FCA liability either. The *Nathan* relator alleged that a pharmaceutical company's off-label promotion of a drug caused non-reimbursable claims to be submitted to Medicare and Medicaid. The relator alleged that 98 prescriptions written by 16 different physicians and submitted to Medicare must have included some false claims, because 93% of the defendant's sales of the drug were for a dosage level that was approved only for narrow, rare uses. According to the relator, the only possible inference from those statistics was that some significant portion of the 98 prescriptions submitted to the government were for off-label uses, and therefore false.

This Court held that such statistics did not plausibly plead a FCA violation. The problem, this Court explained, was that the relator did "not allege facts that *specifically address* the dosage level of any of the 98 prescriptions . . . he has identified." *Id*. at 459 (emphasis added). Instead, by relying only on statistical evidence, the relator "fail[ed] to allege *directly* that any of the identified prescriptions were for off-label uses, instead requiring that a court draw an implausible inference linking general statistics to the 98 prescriptions." *Id.* (emphasis added).

Given that statistical allegations are insufficient to even state a cause of action, they certainly cannot lead to a liability finding at trial. Indeed, appellate courts around the country have consistently rejected statistical arguments as a basis for avoiding summary judgment when a relator has not provided facts demonstrating a claim's falsity. *See, e.g.*, *U.S. ex rel. Crews v. NCS Healthcare of Ill., Inc.*, 460 F.3d 853, 856 (7th Cir. 2006) (rejecting relator's statistical analysis that Medicare must have been doubled billed for some claims and affirming grant of summary judgment to defendants); *U.S. ex rel. Quinn v. Omnicare Inc.*, 382 F.3d 432, 440 (3d Cir. 2004) (same, explaining that "[w]ithout proof of an actual claim, there is no issue of material fact to be decided by a jury"); *U.S. ex rel. Aflatooni v. Kitsap Physicians Serv.*, 314 F.3d 995, 1002-03 (9th Cir. 2002) (same, holding that relator must come to court with a "claim in hand" to avoid summary judgment).

The reasoning from *Nathan*, *Crews*, *Quinn*, and *Aflatooni* underscores that the *sine qua non* of a FCA violation is a claim that is false. And the falsity of a claim submitted based on a doctor's exercise of clinical judgment about a patient's specific medical needs cannot be established based on anything other than an assessment of the patient's specific situation that shows there was no reasonable basis for the doctor's medical judgment under the circumstances. As *Nathan* explains, a relator must show that a "*specific* false claim was presented to the

government for payment"—not that some percentage of claims likely was. 707 F.3d at 456 (emphasis added). The "critical question is whether the defendant caused a false claim to be presented to the government" for payment, not whether there was some broader "fraudulent scheme." *Id*. Statistical sampling, particularly as to decisions of medical judgment that depend on individual patient circumstances, cannot answer what this Court identified in *Nathan* as the "critical question."[4]

The Supreme Court's decision in *Wal-Mart Stores, Inc. v. Dukes*, 131 S. Ct. 2541 (2011), provides further support for affirming the District Court here. In that case, the Supreme Court disapproved of cutting corners in a manner quite similar to that proposed by the relators' statistical sampling request. The Ninth Circuit, before the case reached the Supreme Court, had endorsed a procedure for proving the defendant's liability in a large class action in which:

> A sample set of the class members would be selected, as to whom liability for sex discrimination and the backpay owing as a result would be determined in depositions supervised by a master. The percentage of claims determined to be valid would then be applied to the entire remaining class, and the number of (presumptively) valid claims thus derived would be

[4] The government offers no basis for its suggestion that requiring a claim-by-claim review would somehow serve to "immuniz[e] the largest perpetrators of fraud." U.S. Br. at 39. A miniscule number of courts have ever authorized statistical sampling to prove FCA liability, and yet the government has recovered tens of billions of dollars in settlements and judgments under the statute in the past few decades. *See* Civil Div., U.S. Dep't of Justice, *Fraud Statistics - Overview, October 1, 1987 - September 30, 2015*, at 1-4 (Nov. 23, 2015).

> multiplied by the average backpay award in the sample set to arrive at the entire class recovery—without further individualized proceedings.

Id. at 2561. That procedure is remarkably akin to the procedure proposed by the relators to the District Court: Replace "class members" with "claims" and "sex discrimination" with "falsity," and the passage essentially describes the relators' proposal. The Supreme Court reversed and strongly "disapprove[d] that novel project." *Id*. Such a "Trial by Formula" could not be used to prevent the defendant from litigating all its defenses as to any class member. The same is true here. FCA defendants must be able to litigate all of their defenses against each challenge to a doctor's medical judgment—including demonstrating the reasonableness of that judgment.

The Supreme Court's recent decision in *Tyson Foods, Inc. v. Bouaphakeo*, No. 14-1146 (Mar. 22, 2016), further explains why the Court rejected a statistical approach in *Wal-Mart*. Each class member's claim depended on the specific factual circumstances of her employment—such as which store she had worked in and who her manager was. As a result, if each employee's suit had been brought individually, there would have been "little or no role for representative evidence." Slip op. at 14. Merely wrapping all those individual claims into one suit did not affect whether there was any role for representative evidence in proving liability.

Id.[5] So too here. Relators are litigating claims involving thousands of patient-specific factual circumstances in which hundreds (if not thousands) of doctors exercised clinical judgments across many different hospice facilities. Where, as here, each individual claim would not be amenable to statistical proof, relators cannot override that limitation simply by aggregating many claims.

B. Claims That Depend On Medical Judgment Are Particularly Ill-Suited to Statistical Proof.

Health care claims involving medical judgment are uniquely inappropriate for statistical proof. Relators pursuing such claims are second-guessing a doctor's medical judgment and trying to equate that medical judgment with fraud on the United States. But so long as a doctor's medical opinion about the need for treatment is reasonable, there is no liability under the FCA. *See U.S. ex rel. Hockett v. Columbia/HCA Health care Corp.*, 498 F. Supp. 2d 25, 65 n.29 (D.D.C. 2007) (noting that "at some point, the question of whether a patient should be discharged becomes one of medical opinion, and that where reasonable medical minds might differ over the preferred course of treatment, FCA liability will be

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[5] The situation may be different, as *Tyson Foods* explains, if statistical evidence is necessary "to fill an evidentiary gap created by the [defendant's] failure to keep adequate records." Slip op. at 12. Likewise, the District Court recognized that whether to permit statistical sampling in the FCA context might come out differently if evidence had been destroyed or dissipated. Dkt. No. 296, at 13-14. Of course, that is not the case here: "The patients' medical charts are all intact and available for review by either party." *Id.* at 14.

inappropriate"); *U.S. ex rel. Geschrey v. Generations Health care, LLC*, 922 F. Supp. 2d 695, 703 (N.D. Ill. 2012) (dismissing FCA complaint against a hospice provider because the "[r]elators have not alleged facts demonstrating that the certifying physician did not or could not have believed, based on his or her clinical judgment, that the patient was eligible for hospice care"). As one court has put it, "an FCA complaint about the exercise of [a physician's] judgment [concerning hospice eligibility] must be predicated on the presence of an objectively verifiable fact at odds with the exercise of that judgment, not a matter of subjective clinical analysis." *U.S. ex rel. Wall v. Vista Hospice Care, Inc.*, 778 F. Supp. 2d 709, 718 (N.D. Tex. 2011). *Cf. Harrison*, 176 F.3d at 792 ("Expressions of opinion are not actionable as fraud.").

Hospitals and health care providers subjected to FCA suits must be given the opportunity to defend the exercise of medical judgment underlying each and every claim that they submit for payment. As the District Court observed below, answering the liability question for each of the patients involved in this action "is [a] highly fact-intensive inquiry involving medical testimony after a thorough review of the detailed medical chart of each individual patient." Dkt. No. 296, at 17. That inquiry is simply not amenable to statistical proof.

C. The Reliability of Statistical Sampling, The Costs Of Claim-By-Claim Proof, And Cases Addressing Damages Do Not Change The Analysis.

Relators suggest that the question before the Court "is not whether statistical sampling and extrapolation, in and of itself, is appropriate, but whether the statistical sampling is conducted in a scientifically proven and accepted manner pursuant to the Supreme Court's ruling in *Daubert* [*v. Merrell Dow Pharm., Inc*, 509 U.S. 579 (1993)]." Relators' Br. 11. That is wrong. Whether a relators' expert's statistical opinion can satisfy *Daubert* has no bearing on whether the relator can prove that a doctor's exercise of clinical judgment about a patient's medical needs was so demonstrably wrong as to equate to fraud on the government. Just as the Court's decision in *Nathan* did not turn on whether the relator's alleged statistics were reliable, the question here too is whether that sort of evidence could *ever* be sufficient proof. Similarly, the whole point of the Supreme Court's *Wal-Mart* decision was that a plaintiff cannot substitute statistical proof for actual proof; the analysis did not turn on how the statistics would be computed. The relators' *Daubert* argument is an unavailing attempt at deflection, not a reason to rule in their favor.

Likewise, the FCA burden of proof is not satisfied by statistical sampling just because it would be expensive to actually analyze the medical records connected with a given claim. As explained above, this Court's case law has

established that FCA liability must be proven on a claim-by-claim basis. In a case against a health care provider based on clinical determinations, making that proof may require expert testimony and that expert testimony may be expensive. But courts do not relax substantive standards of liability because they may be hard to meet in a particular case. That puts the cart before the horse: The substantive standard itself, not considerations of convenience or thrift, determines the showing a plaintiff must make.

Moreover, the FCA allows a relator to recoup his "reasonable expenses" if a suit is successful. *See* 31 U.S.C. § 3730(d)(2) (prevailing relator is entitled to "receive an amount for reasonable expenses which the court finds to have been necessarily incurred, plus reasonable attorneys' fees and costs"). A number of courts have awarded expert fees as a component of "reasonable expenses." *See U.S. ex rel. Maxwell v. Kerr-McGee Oil & Gas Corp.*, 793 F. Supp. 2d 1260, 1267-68 (D. Colo. 2011); *U.S. ex rel. Abbott-Burdick v. University Med. Assocs.*, No. 2:96-1676-12, 2002 WL 34236885, at *23 (D. S.C. May 23, 2002). The prospect of recovering expert fees makes it even more unwarranted to relax the FCA's substantive standards of liability simply because the relator has to hire an expert. To the extent relators seek to use statistical sampling to avoid the risk of litigation costs in the event that they lose, such a complaint is not worthy of this Court's solicitude and certainly not a good reason to relax the applicable standard of proof.

Finally, the relators cite to a handful of mostly out-of-circuit district court decisions that are uniformly unhelpful. They address an issue not presented here, whether statistical evidence can be used to prove *damages*.[6] Those decisions thus provide no basis for using statistical sampling and extrapolation to prove the threshold question of *liability*. As the Supreme Court has long made clear, "there is a clear distinction between the measure of proof necessary to establish the fact that petitioner had sustained some damage"—i.e., liability—"and the measure of proof necessary to enable the jury to fix the amount." *Story Parchment Co. v. Paterson Parchment Paper Co.*, 282 U.S. 555, 562 (1931). For the reasons already discussed, FCA relators cannot use statistical sampling to prove liability. Whether a statistical methodology could be used to calculate damages *after* a fact-finder has been presented with evidence that false claims were submitted is not before the Court and should not be addressed until a case squarely presents the issue.

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[6] *See United States v. Fadul*, Civ. No. DKC 11-0385, 2013 WL 781614, at *14 (D. Md. Feb. 28, 2013) (discussing "sampling and extrapolation as a viable method of proving *damages* in cases involving Medicare and Medicaid overpayments where a claim-by-claim review is not practical" (emphasis added)); *U.S. ex rel. Barron v. Deloitte & Touche, LLP*, No. Civ. No. SA-99-CA-1093-FB, 2008 WL 7136869, at *2 (W.D. Tex. Sept. 26, 2008) (discussing "the use of statistical sampling and extrapolation to determine *damages* in a False Claims Act case" (emphasis added)); *Goldstar Med. Servs., Inc. v. Department of Soc. Servs.*, 955 A.2d 15, 31 (Conn. 2008) (approving extrapolation to prove "damages" in non-FCA case); *United States v. Cabrera-Diaz*, 106 F. Supp. 2d 234, 240 (D.P.R. 2000) (approving "proof of *damages* through the use of statistics and statistical sampling" in case where liability had been established through default judgment (emphasis added)).

II. APPROVING STATISTICAL SAMPLING IN CASES CHALLENGING PHYSICIANS' MEDICAL JUDGMENT WOULD EXACERBATE THE EXORBITANT COSTS HOSPITALS ALREADY INCUR DEFENDING AGAINST FALSE CLAIMS ACT SUITS.

FCA litigation already imposes enormous costs on hospitals. Although the government declines to participate in the overwhelming majority of *qui tam* cases, and although the vast majority of declined cases result in no recovery to the United States, hospitals and other FCA defendants have no choice but to incur burdensome and expensive investigation and litigation costs. In this context, permitting statistical sampling to undercut a hospital's ability to defend itself against crippling FCA judgments presents an issue of fundamental fairness.

The number of FCA lawsuits involving health care entities has dramatically increased—from just fifteen cases in 1987 (less than 5% of all FCA cases filed that year) to nearly 450 cases in 2015 (over 60% of the FCA cases filed). *See* Civil Div., U.S. Dep't of Justice, *Fraud Statistics - Overview, October 1, 1987 - September 30, 2015*, at 1-4 (Nov. 23, 2015) ("DOJ Fraud Statistics") (based on fiscal year; health care cases measured by those involving the Department of Health and Human Services as the primary client agency).[7] The number of relator-filed FCA cases has seen a twentyfold increase during this time period—no doubt largely incentivized by the bounties for success, which can reach as high as 30% of

[7] *See* https://www.justice.gov/opa/file/796866/download.

any recovery, as well as attorneys' fees, costs, and reasonable expenses. 31 U.S.C. § 3730(d)(1)-(2); *see* DOJ Fraud Statistics 1-2 (30 *qui tam* cases were filed in 1987; 632 were filed in 2015). Health care suits accounted for nearly 70% of the *qui tam* cases filed in 2015. *Id*.

The United States is an active participant in comparatively few *qui tam* suits, intervening in only 22% from 2006 to 2011. *See* Letter from Jim Esquea, Assistant Sec'y, HHS & Ronald Weich, Assistant Att'y Gen., DOJ, to the Hon. Charles E. Grassley, Senator, U.S. Senate 15 (Jan. 24, 2011)[8]; *see also* U.S. Dep't of Justice, *False Claims Act Cases: Government Intervention in Qui Tam (Whistleblower) Suits* 2 (Apr. 18, 2011)[9] ("Fewer than 25% of filed qui tam actions result in an intervention on any count by the Department of Justice."); R. Scott Oswald & David L. Scher, *DOJ's New 'No Decision' Tactic in 'Qui Tam' Cases Leaves Counsel Guessing*, Bloomberg Law, Aug. 1, 2014[10] (government intervenes in around 22% to 27% of cases). And because most *qui tam* cases involve the federal health care programs, many declined cases name health care providers like AHA's and CHA's members as defendants. *See* GAO, Letter from Laurie E. Ekstrand, Dir., Homeland Sec. & Justice, to the Hon. F. James Sensenbrenner, Jr., Chairman,

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[8] *See* http://www.taf.org/DOJ-HHS-joint-letter-to-Grassley.pdf.

[9] *See* http://www.justice.gov/sites/default/files/usao-edpa/legacy/2011/04/18/fcaprocess2_0.pdf.

[10] *See* http://www.bna.com/dojs-new-no-n17179893168/.

H.R. Comm. on the Judiciary et al., *Information on False Claims Act Litigation* 29 (Jan. 31, 2006) (noting at that time that 754 of the 1770 declined case since 1987 were in the health care field) ("GAO Report").[11]

Declined cases permit relators to put their own pecuniary interests front and center in their litigation strategies. *See Hughes Aircraft Co. v. U.S. ex rel. Schumer*, 520 U.S. 939, 949 (1997) ("[*q*]*ui tam* relators are . . . motivated primarily by prospects of monetary reward rather than the public good"); *see also* Jody Freeman, *The Private Role in Public Governance*, 75 N.Y.U. L. Rev. 543, 574 (2000) (explaining that relators "pursue different goals and respond to different incentives than do public agencies" and have no "direct accountability to the electorate"). Relators' argument that they should be permitted to rely on statistical evidence to cut costs and avoid having to review patients' records exemplifies that trend.

The overwhelming majority of declined health care *qui tam* suits lack merit and thus produce no recovery for the United States. *See* Christina Orsini Broderick, *Qui Tam Provisions and the Public Interest: An Empirical Analysis*, 107 Colum. L. Rev. 949, 975 (2007) (study shows from 1987 to 2004, 92% of declined *qui tam* cases were ultimately dismissed); *see also Riley v. St. Luke's Episcopal Hosp.*, 252 F.3d 749, 767 n.24 (5th Cir. 2001) (Smith, J., dissenting)

[11] *See* http://www.gao.gov/assets/100/93999.pdf.

(noting that "[o]f the 1,966 [of all *qui tam*] cases that the government has refused to join, only 100 have resulted in recoveries (5%)"). Since 1987, only 6% of the total *qui tam* settlements and judgments have come from cases where the government declined to intervene. *See* DOJ Fraud Statistics 2 (calculated by dividing the total recovery in declined *qui tam* cases by the total recovery in all *qui tam* cases). In health care *qui tam* suits, declined cases account for only 4% of recoveries. *Id.* at 4.

This broader context shows why allowing relators to prove liability with statistical sampling would be so damaging. FCA "Trial by Formula" would deprive health care providers of the ability to defend the merits of the medical judgment underlying each individual claim. The loss of that defense, coupled with the already high cost of defending against FCA suits, will force more and more health care providers to settle non-meritorious suits for far more than they are worth. And it will divert money from care for patients, driving up health care costs for everyone. This Court should decline to go down that road.

CONCLUSION

For the foregoing reasons and those in the brief of the Agape entities, the District Court's judgment should be affirmed with respect to the statistical sampling issue.

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Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

This brief complies with the type-volume limitation of Fed. R. App. P. 29(d) because it contains 6,020 words, excluding the parts of the brief exempted by Fed. R. App. P. 32(a)(7)(B)(iii). This brief complies with the typeface requirements of Fed. R. App. P. 32(a)(5) and the type style requirements of Fed. R. App. P. 32(a)(6) because it has been prepared using Microsoft Word in the Times New Roman 14-point typeface.

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I certify that on March 24, 2016, the foregoing was electronically filed through this Court's CM/ECF system, which will send a notice of filing to all registered users.

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